EXHIBIT 2

1: J Clin Immunol. 1996 Sep;16(5):266-71. Related Articles, Links

Viral load, CD4 percentage, and delayed-type hypersensitivity in subjects receiving the HIV-1 immunogen and antiviral drug therapy.

Moss RB, Ferre F, Levine A, Turner J, Jensen FC, Daigle AE, Richieri SP, Truckenbrod A, Trauger RJ, Carlo DJ, Salk J.

Immune Response Corporation, Carlsbad, California 92008, USA.

Two trials of subjects inoculated with the inactivated, gp120-depleted HIV-1 Immunogen are reported. In one study, in which 19 subjects received ZDV and 8 subjects received ddI, treatment with the HIV-1 Immunogen did not affect the pharmacokinetic parameters of the antiviral drugs. In another study, 65 subjects who were previously immunized with the HIV-1 Immunogen over a mean period of 4.0 years (range, 1.2-5.4 years) received inoculations at 0 and 6 months. At some point during this 48-week study, 72% of the subjects (47/65) were receiving antiviral drug therapy. The HIV-1 DNA load in CD4 cells and CD4 percentage were found to be stable over the 48-week period. Delayed-type hypersensitivity to HIV-1 antigens increased after two inoculations with the HIV-1 Immunogen. In these two trials, no serious treatment-related adverse events were documented in the subjects. The two studies presented herein are the first to suggest that an immune-based therapy such as the HIV-1 Immunogen can be combined safely with antiviral drugs, supporting further study to evaluate the clinical utility of this approach.

Publication Types:
- Clinical Trial

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